SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

[Invented name] 75 microgram film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 75 microgram desogestrel.
Excipient with known effect: Each film-coated tablet contains 54.345 mg lactose monohydrate.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.
White to off-white, circular, biconvex, film-coated tablets without embossing with a diameter of 5.6 ± 0.2 mm.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Contraception.

4.2 Posology and method of administration

Posology
To achieve contraceptive effectiveness, [Invented name] must be used as directed (see 'How to take [Invented name]' and 'How to start [Invented name]').

Special populations
Renal impairment
No clinical studies have been performed in patients with renal impairment.

Hepatic impairment
No clinical studies have been performed in patients with hepatic insufficiency. Since the metabolism of steroid hormones might be impaired in patients with severe hepatic disease, the use of desogestrel in these women is not indicated as long as liver function values have not returned to normal (see section 4.3).

Paediatric population
The safety and efficacy of desogestrel in adolescents below 18 years has not been established. No data are available.

Method of administration
Oral use.

How to take [Invented name]
Tablets must be taken every day at about the same time so that the interval between two tablets always is 24 hours. The first tablet should be taken on the first day of menstrual bleeding. Thereafter one tablet each day is to be taken continuously, without taking any notice on possible bleeding. A new blister is started directly the day after the previous one.

How to start [Invented name]
No preceding hormonal contraceptive use [in the past month]
Tablet-taking has to start on day 1 of the woman's natural cycle (day 1 is the first day of her menstrual bleeding). Starting on days 2 – 5 is allowed, but during the first cycle a barrier method is recommended for the first 7 days of tablet-taking.

Following first-trimester abortion
After first-trimester abortion it is recommended to start immediately. In that case there is no need to use an additional method of contraception.

Following delivery or second-trimester abortion
The woman should be advised to start any day between day 21 to 28 after delivery or second-trimester abortion. When starting later, she should be advised to additionally use a barrier method until completion of the first 7 days of tablet-taking. However, if intercourse has already occurred, pregnancy should be excluded before the actual start of [Invented name] use or the woman has to wait for her first menstrual period.
For additional information for breast-feeding women see section 4.6.

How to start [Invented name] when changing from other contraceptive methods
Changing from a combined hormonal contraceptive (combined oral contraceptive (COC), vaginal ring, or transdermal patch)
The woman should start [Invented name] preferably on the day after the last active tablet (the last tablet containing the active substances) of her previous COC or on the day of removal of her vaginal ring or transdermal patch. In these cases, the use of an additional contraceptive is not necessary.
The woman may also start at the latest on the day following the usual tablet-free, patch-free, ring-free, or placebo tablet interval of her previous combined hormonal contraceptive, but during the first 7 days of tablet-taking an additional barrier method is recommended.

Changing from a progestogen-only-method (minipill, injection, implant or from a progestogen-releasing intrauterine system [IUS])
The woman may switch any day from the minipill (from an implant or the IUS on the day of its removal, from an injectable when the next injection would be due), there is no need to use an additional method of contraception.

Management of missed tablets
Contraceptive protection may be reduced if more than 36 hours have elapsed between two tablets. If the user is less than 12 hours late in taking any tablet, the missed tablet should be taken as soon as it is remembered and the next tablet should be taken at the usual time. If she is more than 12 hours late, she should use an additional method of contraception for the next 7 days. If tablets were missed in the first week after initiation of [Invented name] and intercourse took place in the week before the tablets were missed, the possibility of a pregnancy should be considered.

Advice in case of gastrointestinal disturbances
In case of severe gastro-intestinal disturbance, absorption may not be complete and additional contraceptive measures should be taken. If vomiting occurs within 3 – 4 hours after tablet-taking, absorption may not be complete. In such an event, the advice concerning missed tablets, as given in section 4.2 is applicable.

Treatment surveillance
Before prescription, a thorough case history should be taken and a thorough gynaecological examination is recommended to exclude pregnancy. Bleeding disturbances, such as oligomenorrhoea and amenorrhoea should be investigated before prescription. The interval between check-ups depends on the circumstances in each individual case. If the prescribed product may conceivably influence latent or manifest disease (see section 4.4), the control examinations should be timed accordingly. Despite the fact that [Invented name] is taken regularly, bleeding disturbances may occur. If bleeding is very frequent and irregular, another contraceptive method should be considered. If the symptoms persist, an organic cause should be ruled out.
Management of amenorrhoea during treatment depends on whether or not the tablets have been taken in accordance with the instructions and may include a pregnancy test.

The treatment should be stopped if a pregnancy occurs.

Women should be advised that [Invented name] does not protect against HIV (AIDS) and other sexually transmitted diseases.

4.3 Contraindications

- Active venous thromboembolic disorder.
- Presence or history of severe hepatic disease as long as liver function values have not returned to normal.
- Known or suspected sex-steroid sensitive malignancies.
- Undiagnosed vaginal bleeding.
- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

If any of the conditions/risk factors mentioned below is present, the benefits of progestogen use should be weighed against the possible risks for each individual woman and discussed with the woman before she decides to start with [Invented name]. In the event of aggravation, exacerbation, or first appearance of any of these conditions, the woman should contact her physician. The physician should then decide on whether the use of [Invented name] should be discontinued.
The risk for breast cancer increases in general with increasing age. During use of combined oral contraceptives (COCs) the risk of having breast cancer diagnosed is slightly increased. This increased risk disappears gradually within 10 years after discontinuation of COC use and is not related to the duration of use, but to the age of the woman when using the COC. The expected number of cases diagnosed per 10 000 women who use COCs (up to 10 years after stopping) relative to never users over the same period has been calculated for the respective age groups and is presented in the table below.

Age group	Expected cases COC-users	Expected cases non-users
16 – 19 years	4.5	4
20 – 24 years	17.5	16
25 – 29 years	48.7	44
30 – 34 years	110	100
35 – 39 years	180	160
40 – 44 years	260	230

The risk in users of progestogen-only contraceptives (POCs), such as desogestrel, is possibly of similar magnitude as that associated with COCs. However, for POCs the evidence is less conclusive. Compared to the risk of getting breast cancer ever in life, the increased risk associated with COCs is

low. The cases of breast cancer diagnosed in COC users tend to be less advanced than in those who have not used COCs. The increased risk in COC users may be due to an earlier diagnosis, biological effects of the pill or a combination of both.
Since a biological effect of progestogens on liver cancer cannot be excluded an individual benefit/risk assessment should be made in women with liver cancer.
When acute or chronic disturbances of liver function occur the woman should be referred to a specialist for examination and advice.
Epidemiological investigations have associated the use of COCs with an increased incidence of venous thromboembolism (VTE, deep venous thrombosis and pulmonary embolism). Although the clinical relevance of this finding for desogestrel used as a contraceptive in the absence of an oestrogenic component is unknown, [Invented name] should be discontinued in the event of a thrombosis. Discontinuation of [Invented name] should also be considered in case of long-term immobilisation due to surgery or illness. Women with a history of thrombo-embolic disorders should be made aware of the possibility of a recurrence.
Although progestogens may have an effect on peripheral insulin resistance and glucose tolerance, there is no evidence for a need to alter the therapeutic regimen in diabetics using progestogen-only pills. However, diabetic patients should be carefully observed during the first months of use.
If a sustained hypertension develops during the use of [Invented name], or if a significant increase in blood pressure does not adequately respond to antihypertensive therapy, the discontinuation of [Invented name] should be considered.
Treatment with desogestrel leads to decreased estradiol serum levels, to a level corresponding with the early follicular phase. It is as yet unknown whether the decrease has any clinically relevant effect on bone mineral density.
The protection with traditional progestogen-only pills against ectopic pregnancies is not as good as with combined oral contraceptives, which has been associated with the frequent occurrence of ovulations during the use of progestogen-only pills. Despite the fact that desogestrel consistently inhibits ovulation, ectopic pregnancy should be taken into account in the differential diagnosis if the woman gets amenorrhoea or abdominal pain.
Chloasma may occasionally occur, especially in women with a history of *chloasma gravidarum*. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation whilst taking [Invented name].
The following conditions have been reported both during pregnancy and during sex steroid use, but an association with the use of progestogens has not been established: jaundice and/or pruritus related to cholestasis; gallstone formation; porphyria; systemic lupus erythematosus; haemolytic uraemic syndrome; Sydenham's chorea; herpes gestationis; otosclerosis-related hearing loss; (hereditary) angioedema.
The efficacy of desogestrel may be reduced in the event of missed tablets (see section 4.2), gastro-intestinal disturbances (see section 4.2), or concomitant medications that decrease the plasma concentration of etonogestrel, the active metabolite of desogestrel (see section 4.5).
Depressed mood and depression are well-known undesirable effects of hormonal contraceptive use (see section 4.8). Depression can be serious and is a well-known risk factor for suicidal behaviour and suicide. Women should be advised to contact their physician in case of mood changes and depressive symptoms, including shortly after initiating the treatment.

Laboratory tests
Data obtained with COCs have shown that contraceptive steroids may influence the results of certain laboratory tests, including biochemical parameters of liver, thyroid, adrenal and renal function, serum levels of (carrier) proteins, e.g. corticosteroid binding globulin and lipid/lipoprotein fractions, parameters of carbohydrate metabolism and parameters of coagulation and fibrinolysis. The changes generally remain within the normal range. To what extent this also applies to progestogen-only contraceptives is not known.

[Invented name] contains lactose monohydrate
Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Interactions
Note: The prescribing information of concomitant medications should be consulted to identify potential interactions.

Effect of other medicinal products on desogestrel
Interactions can occur with medicinal products that induce microsomal enzymes, which can result in increased clearance of sex hormones and may lead to breakthrough bleeding and/or contraceptive failure.

Management
Enzyme induction can occur after a few days of treatment. Maximum enzyme induction is generally observed within a few weeks. After drug therapy is discontinued, enzyme induction can last for about 4 weeks.

Short-term treatment
Women on treatment with hepatic enzyme-inducing medicinal or herbal products should be advised that the efficacy of desogestrel may be reduced. A barrier contraceptive method should be used in addition to desogestrel. The barrier method must be used during the whole time of concomitant drug therapy and for 28 days after discontinuation of the hepatic enzyme-inducing medicinal product.

Long-term treatment
For women on long-term therapy with enzyme-inducing medicinal products, an alternative method of contraception unaffected by enzyme-inducing medicinal products should be considered.

Substances increasing the clearance of contraceptive hormones (diminished contraceptive efficacy by enzyme induction) e.g.
Barbiturates, bosentan, carbamazepine, phenytoin, primidone, rifampicin, efavirenz and possibly also felbamate, griseofulvin, oxcarbazepine, topiramate, rifabutin and products containing the herbal remedy St. John's Wort (*Hypericum Perforatum*).

Substances with variable effects on the clearance of contraceptive hormones
When co-administered with hormonal contraceptives, many combinations of HIV protease inhibitors (e.g. ritonavir, nelfinavir) and non-nucleoside reverse transcriptase inhibitors (e.g. nevirapine) and/or combinations with Hepatitis C virus (HCV) medicinal products (e.g. boceprevir, telaprevir), can increase or decrease plasma concentrations of progestins. The net effect of these changes may be clinically relevant in some cases.
Therefore, the prescribing information of concomitant HIV/HCV medications should be consulted to identify potential interactions and any related recommendations. In case of any doubt, an additional barrier contraceptive method should be used by women on protease inhibitor or non-nucleoside reverse transcriptase inhibitor therapy.

Substances decreasing the clearance of contraceptive hormones (enzyme inhibitors)
Concomitant administration of strong (e.g. ketoconazole, itraconazole, clarithromycin) or moderate (e.g. fluconazole, diltiazem, erythromycin) CYP3A4 inhibitors may increase the serum concentrations of progestins, including etonogestrel, the active metabolite of desogestrel.

Effects of desogestrel on other medicinal products
Hormonal contraceptives may interfere with the metabolism of other drugs. Accordingly, plasma and tissue concentrations of other active substances may either increase (e.g. ciclosporine) or decrease (e.g. lamotrigine).

4.6 Fertility, pregnancy and lactation

Pregnancy
[Invented name] is not indicated during pregnancy. If pregnancy occurs during treatment with [Invented name], further intake should be stopped.
Animal studies have shown that very high doses of progestogenic substances may cause masculinisation of female foetuses.
Extensive epidemiological studies have revealed neither an increased risk of birth defects in children born to women who used COCs prior to pregnancy, nor a teratogenic effect when COCs were taken inadvertently during early pregnancy. Pharmacovigilance data collected with various desogestrel-containing COCs also do not indicate an increased risk.

Breast-feeding
Based on clinical study data, desogestrel does not appear to influence the production or the quality (protein, lactose, or fat concentrations) of breast milk. However, there have been infrequent postmarketing reports of a decrease in breast milk production while using desogestrel. Small amounts of etonogestrel are excreted in the breast milk. As a result, 0.01 – 0.05 µg etonogestrel per kg body weight per day may be ingested by the child (based on an estimated milk ingestion of 150 ml/kg/day). Like other progestogen-only pills, [Invented name] can be used during breast-feeding.
Limited long-term follow-up data are available on children, whose mothers started using desogestrel during the 4th to 8th week post-partum. They were breast-fed for 7 months and followed up to 1.5 years (n = 32) or to 2.5 years (n = 14) of age. Evaluation of growth and physical and psychomotor development did not indicate any differences in comparison to nursing infants, whose mother used a copper-IUD. Based on the available data [Invented name] may be used during lactation. The development and growth of a nursing infant, whose mother uses [Invented name], should however be carefully observed.

Fertility
[Invented name] is indicated for the prevention of pregnancy. For information on return to fertility (ovulation), see section 5.1.

4.7 Effects on ability to drive and use machines

[Invented name] has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The most commonly reported undesirable effect in the clinical trials is bleeding irregularity. Some kind of bleeding irregularity has been reported in up to 50% of women using desogestrel. Since desogestrel causes ovulation inhibition close to 100%, in contrast to other progestogen-only pills, irregular bleeding is more common than with other progestogen-only pills. In 20 – 30% of the women, bleeding may become more frequent, whereas in another 20% bleeding may become less frequent or totally absent. Vaginal bleeding may also be of longer duration. After a couple of months of treatment, bleedings tend to become less frequent. Information, counselling and a bleeding diary can improve the woman's acceptance of the bleeding pattern.
The most commonly reported other undesirable effects in the clinical trials with desogestrel (> 2.5%) were acne, mood changes, breast pain, nausea and weight increase. The undesirable effects are mentioned in the table below.

All undesirable effects are listed by system-organ class and frequency: common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000) and not known (cannot be estimated from the available data).

System Organ Class (MedDRA)*	**Frequency of adverse reactions**			
	Common	**Uncommon**	**Rare**	**Not known**
Infections and infestations		Vaginal infection		
Immune system disorders				Hypersensitivity reactions, including angioedema and anaphylaxis
Psychiatric disorders	Mood altered, Depressed mood, Libido decreased			
Nervous system disorders	Headache			
Eye disorders		Contact lens intolerance		
Gastrointestinal disorders	Nausea	Vomiting		
Skin and subcutaneous tissue disorders	Acne	Alopecia	Rash, Urticaria, Erythema nodosum	
Reproductive system and breast disorders	Breast pain, Menstruation irregular, Amenorrhoea	Dysmenorrhoea, Ovarian cyst		
General disorders and administration site condition		Fatigue		
Investigations	Weight increased			

* MedDRA version 9.0

Breast discharge may occur during use of desogestrel. On rare occasions, ectopic pregnancies have been reported (see section 4.4). In addition, aggravation of hereditary angioedema may occur (see section 4.4).
In women using (combined) oral contraceptives a number of (serious) undesirable effects have been reported. These include venous thromboembolic disorders, arterial thromboembolic disorders, hormone-dependent tumours (e.g. liver tumours, breast cancer) and chloasma, some of which are discussed in more detail in section 4.4.
Breakthrough bleeding and/or contraceptive failure may result from interactions of other drugs (enzyme inducers) with hormonal contraceptives (see section 4.5).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

There have been no reports of serious deleterious effects from overdose. Symptoms that may occur in this case are nausea, vomiting and, in young girls, slight vaginal bleeding. There are no antidotes and further treatment should be symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: hormonal contraceptives for systemic use, ATC code: G03AC09

Mechanism of action
[Invented name] is a progestogen-only pill, which contains the progestogen desogestrel. Like other progestogen-only pills, desogestrel can be used for women who may not or do not want to use oestrogens. In contrast to traditional progestogen-only pills, the contraceptive effect of desogestrel is achieved primarily by inhibition of ovulation. Other effects include increased viscosity of the cervical mucus.

Clinical efficacy and safety
When studied for 2 cycles, using a definition of ovulation as a progesterone level greater than 16 nmol/L for 5 consecutive days, the ovulation incidence was found to be 1% (1/103) with a 95% confidence interval of 0.02% – 5.29% in the ITT group (user and method failures). Ovulation inhibition was achieved from the first cycle of use. In this study, when desogestrel was discontinued after 2 cycles (56 continuous days) ovulation occurred on average after 17 days (range 7 – 30 days).
In a comparative efficacy trial (which allowed a maximum time of 3 hours for missed pills), the overall ITT Pearl-Index found for desogestrel was 0.4 (95% confidence interval 0.09 – 1.20), compared to 1.6 (95% confidence interval 0.42 – 3.96) for 30 µg levonorgestrel.
The Pearl-Index for desogestrel is comparable to the one historically found for COCs in the general COC-using population.
Treatment with desogestrel leads to decreased estradiol levels, to a level corresponding to the early follicular phase. No clinically relevant effects on carbohydrate metabolism, lipid metabolism and haemostasis have been observed.

Paediatric population
No clinical data on efficacy and safety are available in adolescents below 18 years.

5.2 Pharmacokinetic properties

Absorption
After oral dosing of [Invented name] desogestrel (DSG) is rapidly absorbed and converted into etonogestrel (ENG). Under steady-state conditions, peak serum levels are reached 1.8 hours after tablet-intake and the absolute bioavailability of ENG is approximately 70%.

Distribution
ENG is 95.5 – 99% bound to serum proteins, predominantly to albumin and to a lesser extent to SHBG.

Biotransformation

DSG is metabolised via hydroxylation and dehydrogenation to the active metabolite ENG. ENG is primarily metabolised by the cytochrome P450 3A (CYP3A) isoenzyme and subsequently conjugated with sulphate and glucuronide.

Elimination
ENG is eliminated with a mean half-life of approximately 30 hours, with no difference between single and multiple dosing. Steady-state levels in plasma are reached after 4 – 5 days. The serum clearance after i.v. administration of ENG is approximately 10 l/h. Excretion of ENG and its metabolites either as free steroid or as conjugates, is with urine and faeces (ratio 1.5:1). In lactating women, ENG is excreted in breast milk with a milk/serum ratio of 0.37 – 0.55. Based on these data and an estimated milk intake of 150 ml/kg/day, 0.01 – 0.05 µg etonogestrel may be ingested by the infant.

Special populations
Renal impairment
No studies were performed to evaluate the effect of renal disease on the pharmacokinetics of DSG.

Hepatic impairment
No studies were conducted to evaluate the effect of hepatic disease on the pharmacokinetics of DSG. However, steroid hormones may be poorly metabolized in women with impaired liver function.

Ethnic groups
No studies were performed to assess pharmacokinetics in ethnic groups.

5.3 Preclinical safety data

Toxicological studies did not reveal any effects other than those, which can be explained from the hormonal properties of desogestrel.

Environmental risk assessment (ERA)
The active substance etonogestrel shows an environmental risk to fish.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core
Lactose monohydrate,
Maize starch,
Povidone K30,
Stearic acid,
RRR-α-tocopherol,
Silica, colloidal anhydrous.

Film coating
Hypromellose,
Macrogol 400,
Talc,
Titanium dioxide (E171).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

PVC/TE/PVdC film/Aluminium foil blister, a carton, packaging insert.
Each blister contains 28 tablets. Each carton contains 1, 3 or 6 blisters.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

The active substance etonogestrel shows an environmental risk to fish.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

[To be completed nationally]

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

[To be completed nationally]

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON BOX

1. NAME OF THE MEDICINAL PRODUCT

[Invented name] 75 microgram film-coated tablets
desogestrel

2. STATEMENT OF ACTIVE SUBSTANCE

Each film-coated tablet contains 75 microgram desogestrel.

3. LIST OF EXCIPIENTS

It also contains lactose monohydrate.

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablet

1×28 film-coated tablets
3×28 film-coated tablets
6×28 film-coated tablets

5. METHOD AND ROUTE OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

12. MARKETING AUTHORISATION NUMBER(S)

Reg. No.:

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[Invented name]

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC
SN
NN

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTERS

1. NAME OF THE MEDICINAL PRODUCT

[Invented name] 75 microgram film-coated tablets
desogestrel

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Logo MAH

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Batch

5. OTHER

Days of the week above each tablet

Mon -> Tue -> Wed -> Thu -> Fri -> Sat -> Sun -> Mon -> Tue -> Wed ->Thu -> Fri -> Sat -> Sun ->
Mon -> Tue -> Wed -> Thu -> Fri -> Sat -> Sun -> Mon -> Tue -> Wed -> Thu -> Fri -> Sat -> Sun->

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

[Invented name] 75 microgram film-coated tablets
desogestrel

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [Invented name] is and what it is used for

[Invented name] is used to prevent pregnancy. [Invented name] contains a small amount of one type of female sex hormone, the progestogen **desogestrel**. For this reason [Invented name] is called a progestogen-only-pill (POP). Contrary to the combined pill, the POP does not contain an oestrogen hormone next to the progestogen.
Most POPs work primarily by preventing the sperm cells from entering the womb but do not always prevent the egg cell from ripening, which is the primary action of combined pills. [Invented name] is distinct from most POPs in having a dose that in most cases is high enough to prevent the egg cell from ripening. As a result, [Invented name] provides high contraceptive efficacy.
In contrast to the combined pill, [Invented name] can be used by women who do not tolerate oestrogens and by women who are breast feeding. A disadvantage is that vaginal bleeding may occur at irregular intervals during the use of [Invented name]. You also may not have any bleeding at all.

2. What you need to know before you take [Invented name]

[Invented name], like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

Do not take [Invented name]
- if you are allergic to desogestrel, or any of the other ingredients of this medicine (listed in section 6).
- if you have a thrombosis. Thrombosis is the formation of a blood clot in a blood vessel (e.g. of the legs (deep venous thrombosis) or the lungs (pulmonary embolism)).
- if you have or have had jaundice (yellowing of the skin) or severe liver disease and your liver function is still not normal.
- if you have or are suspected to have a cancer that is sensitive to sex-steroids, such as certain types of breast cancer.

– if you have any unexplained vaginal bleeding.

Tell your doctor before you start to use [Invented name] if any of these conditions apply to you. Your doctor may advise you to use a non-hormonal method of birth control. Consult your doctor immediately if any of these conditions appear for the first time while using [Invented name].

Warnings and precautions
Talk to your doctor before taking [Invented name], if
– you have ever had breast cancer.
– you have liver cancer, since a possible effect of [Invented name] cannot be excluded.
– you have ever had a thrombosis.
– you have diabetes.
– you suffer from epilepsy (see section 'Other medicines and [Invented name]').
– you suffer from tuberculosis (see section 'Other medicines and [Invented name]').
– you have high blood pressure.
– you have or have had chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face); if so, avoid too much exposure to the sun or ultraviolet radiation.

When [Invented name] is used in the presence of any of these conditions, you may need to be kept under close observation. Your doctor can explain what to do.

Breast cancer
Regularly check your breasts and contact your doctor as soon as possible if you feel any lump in your breasts.
Breast cancer has been found slightly more often in women who take the Pill than in women of the same age who do not take the Pill. If women stop taking the Pill, the risk gradually decreases, so that 10 years after stopping the risk is the same as for women who have never taken the Pill. Breast cancer is rare under 40 years of age but the risk increases as the woman gets older. Therefore, the extra number of breast cancers diagnosed is higher if the age until which the woman continues to take the Pill is higher. How long she takes the Pill is less important.
In every 10 000 women who take the Pill for up to 5 years but stop taking it by the age of 20, there would be less than 1 extra case of breast cancer found up to 10 years after stopping, in addition to the 4 cases normally diagnosed in this age group. Likewise, in 10 000 women who take the Pill for up to 5 years but stop taking it by the age of 30, there would be 5 extra cases in addition to the 44 cases normally diagnosed. In 10 000 women who take the Pill for up to 5 years but stop taking it by the age of 40, there would be 20 extra cases in addition to the 160 cases normally diagnosed.
The risk of breast cancer in users of progestogen-only pills like [Invented name] is believed to be similar to that in women who use the Pill, but the evidence is less conclusive.
Breast cancers found in women who take the Pill, seem less likely to have spread than breast cancers found in women who do not take the Pill. It is not known whether the difference in breast cancer risk is caused by the Pill. It may be that the women were examined more often, so that the breast cancer is noticed earlier.

Thrombosis
See your doctor immediately, if you notice possible signs of a thrombosis (see also 'Regular check-ups').
Thrombosis is the formation of a blood clot, which may block a blood vessel. A thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis). If this clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs, causing a so-called 'pulmonary embolism'. As a result, fatal situations may occur. Deep venous thrombosis is a rare occurrence. It can develop whether or not you are taking the Pill. It can also happen if you become pregnant.
The risk is higher in Pill-users than in non-users. The risk with progestogen-only pills like [Invented name] is believed to be lower than in users of Pills that also contain oestrogens (combined Pills).

Psychiatric disorders
Some women using hormonal contraceptives including [Invented name] have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

Children and adolescents
No clinical data on efficacy and safety are available in adolescents below 18 years.

Other medicines and [Invented name]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines or herbal products. Also tell any other doctor or dentist who prescribes another medicine (or your pharmacist) that you take [Invented name]. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long or whether the use of another medicine you need must be changed.
Some medicines
- can have an influence on the blood levels of [Invented name].
- can make it **less effective in preventing pregnancy**.
- can cause unexpected bleeding.

These include medicines used for the treatment of:
- Epilepsy (e.g. primidone, phenytoin, carbamazepine, oxcarbazepine, felbamate, topiramate and phenobarbital).
- Tuberculosis (e.g. rifampicin, rifabutin).
- HIV infections (e.g. ritonavir, nelfinavir, nevirapine, efavirenz).
- Hepatitis C virus infection (e.g. boceprevir, telaprevir)
- Certain fungal or bacterial infections (e.g. griseofulvin, ketoconazole, itraconazole, fluconazole, clarithromycin, erythromycin).
- High blood pressure in the blood vessels of the lungs (bosentan).
- Depressive moods (the herbal remedy St. John's Wort)
- High blood pressure (hypertension), angina or certain heart rhythm disorders (e.g. diltiazem).

If you are taking medicines or herbal products that might make [Invented name] less effective, a barrier contraceptive method should also be used. Since the effect of another medicine on [Invented name] may last up to 28 days after stopping the medicine, it is necessary to use the additional barrier contraceptive method for that long. Your doctor can tell you if you need to take additional contraceptive precautions and if so, for how long.

[Invented name] may also interfere with how other medicines work, causing either an increase in effect (e.g. medicines containing ciclosporine) or a decrease in effect (e.g. lamotrigine).

Pregnancy, breast-feeding and fertility
Pregnancy
Do not use [Invented name] if you are pregnant, or think you may be pregnant.

Breast-feeding
[Invented name] may be used while you are breast-feeding. [Invented name] does not appear to influence the production or the quality of breast milk. However, there have been infrequent reports of a decrease in breast milk production while using desogestrel. A small amount of the active substance of [Invented name] passes over into the milk.

The health of children breast-fed for 7 months whose mothers were using desogestrel has been studied up to 2.5 years of age. No effects on the growth and development of the children were observed.
If you are breast-feeding and want to use [Invented name], please contact your doctor.

Driving and using machines
There are no indications of any effect of the use of [Invented name] on alertness and concentration.

[Invented name] contains lactose monohydrate (milk sugar)
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Regular check-ups
When you are using [Invented name], your doctor will tell you to return for regular check-ups. In general, the frequency and nature of these check-ups will depend on your personal situation.

Contact your doctor as soon as possible if
- you have severe pain or swelling in either of your legs, unexplained pains in the chest, breathlessness, an unusual cough, especially when you cough up blood (possibly indicating a **thrombosis**).
- you have a sudden, severe stomach ache or look jaundiced (possibly indicating **liver problems**).
- you feel a lump in your breast (possibly indicating **breast cancer**).
- you have a sudden or severe pain in the lower abdomen or stomach area (possibly indicating an **ectopic pregnancy**, this is a pregnancy outside the womb).
- you are to be immobilised or are to have surgery (consult your doctor at least four weeks in advance).
- you have unusual, heavy vaginal bleeding.
- you suspect that you are **pregnant**.

3. How to take [Invented name]

When and how to take the tablets
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The [Invented name] pack contains 28 tablets. Arrows are printed on the front side of the pack, between the tablets. If you turn over your pack, and look at the back side, you will see the days of the week printed on the foil. Each day corresponds with one tablet.
Every time you start a new pack of [Invented name], take a tablet from the top row. Don't start with just any tablet. For example if you start on a Wednesday, you must take the tablet from the top row marked (at the back) with WED. Continue to take one tablet a day until the pack is empty, always following the direction indicated by the arrows. By looking at the back of your pack you can easily check if you have already taken your tablet on a particular day.
Take your tablet each day at about the same time. Swallow the tablet whole, with water. You may have some bleeding during the use of [Invented name], but you must continue to take your tablets as normal. When a pack is empty, you must start with a new pack of [Invented name] on the next day – thus without interruption and without waiting for a bleed.

Starting your first pack of [Invented name]
- When no hormonal contraceptive has been used in the past month

Wait for your period to begin. On the first day of your period take the first [Invented name] tablet. You need not take extra contraceptive precautions. You may also start on days 2 – 5 of your cycle, but in that case make sure you also use an additional contraceptive method (barrier method) for the first 7 days of tablet-taking.

- When changing from a combined pill, vaginal ring, or transdermal patch
  You can start taking [Invented name] on the day after you take the last tablet from the present Pill pack, or on the day of removal of your vaginal ring or patch (this means no tablet-, ring- or patch-free break). If your present Pill pack also contains inactive tablets you can start [Invented name] on the day after taking the last active tablet (if you are not sure which this is, ask your doctor or pharmacist). If you follow these instructions, you need not take extra contraceptive precautions. You can also start at the latest the day following the tablet-, ring-, patch-free break, or placebo tablet interval, of your present contraceptive. If you follow these instructions, make sure you use an additional contraceptive method (barrier method) for the first 7 days of tablet-taking.

- When changing from another progestogen-only pill
  You may stop taking it any day and start taking [Invented name] right away. You need not take extra contraceptive precautions.

- When changing from an injectable or implant or a progestogen-releasing intrauterine device (IUD)
  Start using [Invented name] when your next injection is due or on the day that your implant or your IUD is removed. You need not take extra contraceptive precautions.

- After having a baby:
  You can start [Invented name] between 21 to 28 days after the birth of your baby. If you start later, make sure you use an additional contraceptive method (barrier method) until you have completed the first 7 days of tablet-taking. However, if intercourse has already occurred, pregnancy should be excluded before starting [Invented name] use. Additional information for breast-feeding women can be found in 'Pregnancy, breast-feeding and fertility' in section 2. Your doctor can also advise you.

- After a miscarriage or an abortion:
  Your doctor will advise you.

If you forget to take [Invented name]

- If you are **less than 12 hours** late in taking a tablet, the reliability of [Invented name] is maintained. Take the missed tablet as soon as you remember and take the next tablets at the usual times.
- If you are **more than 12 hours** late in taking any tablet, the reliability of [Invented name] may be reduced. The more consecutive tablets you have missed, the higher the risk that the contraceptive efficacy is decreased. Take the last missed tablet as soon as you remember and take the next tablets at the usual times. Use an additional contraceptive method (barrier method) too for the next 7 days of tablet-taking. If you missed one or more tablets in the first week of tablet-intake and had intercourse in the week before missing the tablets, there is a possibility of becoming pregnant. Ask your doctor for advice.

If you suffer from gastro-intestinal disturbances (e.g. vomiting, severe diarrhoea)
Follow the advice for missed tablets in the section above. If you vomit or use medical charcoal within 3 – 4 hours after taking your [Invented name] tablet or have severe diarrhoea, the active ingredient may not have been completely absorbed.

If you take more [Invented name] than you should

There have been no reports of serious harmful effects from taking too many [Invented name] tablets at one time. Symptoms that may occur are nausea, vomiting and, in young girls, slight vaginal bleeding. For more information ask your doctor for advice.

If you stop taking [Invented name]
You can stop taking [Invented name] whenever you want. From the day you stop you are no longer protected against pregnancy.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious undesirable effects associated with the use of [Invented name] are described in the paragraphs 'Breast cancer' and 'Thrombosis' in section 2 'What you need to know before you take [Invented name]'. Please read this section for additional information and consult your doctor at once where appropriate.

You should see your doctor immediately if you experience symptoms of allergic reaction (hypersensitivity) or angioedema and/or anaphylaxis, such as
- swollen face, lips, tongue and/or pharynx
- difficulty to swallow
- difficulties to breathe.

Vaginal bleeding may occur at irregular intervals during the use of desogestrel. This may be just slight staining which may not even require a pad, or heavier bleeding, which looks rather like a scanty period and requires sanitary protection. You may also not have any bleeding at all. The irregular bleedings are not a sign that the contraceptive protection of desogestrel is decreased. In general, you need not take any action; just continue to take [Invented name]. If, however, bleeding is heavy or prolonged you should consult your doctor.

Following side effects have been reported

Common (may affect up to 1 in 10 women)	Uncommon (may affect up to 1 in 100 women)	Rare (may affect up to 1 in 1,000 women)	Not known (cannot be estimated from the available data)
– mood altered, depressed mood, decreased sexual drive (libido)	– infection of the vagina	– rash, hives, painful blue-red skin lumps (erythema nodosum) (these are skin reactions)	– allergic reaction
– headache	– difficulties in wearing contact lenses		
– nausea	– vomiting		
– acne	– hair loss		
– breast pain, irregular or no menstruation	– painful menstruation, ovarian cyst		

– increased body weight	– tiredness		

Apart from these side effects, breast secretion may occur.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton or blister after 'EXP'. The expiry date refers to the last day of that month.
Do not store above 30°C.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [Invented name] contains
The active substance is: desogestrel (75 microgram).
The other ingredients are: Tablet core: lactose monohydrate; maize starch; povidone K30; stearic acid; RRR-α-tocopherol; silica, colloidal anhydrous.
Film coating: hypromellose; macrogol 400; talc; titanium dioxide (E171).

What [Invented name] looks like and contents of the pack
One blister pack of [Invented name] contains 28 white to off-white, circular, biconvex, film-coated tablets without embossing with a diameter of 5.6 ± 0.2 mm packed in PVC/TE/PVdC film/Aluminium foil blister in a carton with packaging insert.
Each blister contains 28 tablets. Each carton contains 1, 3 or 6 blisters.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

Czech Republic	SECULACT
Italy	Desogestrel Zentiva

This leaflet was last revised in {MM/YYYY}.